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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jie Zhang

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/954,904	<b>Applicant(s)</b> ZHANG ET AL.	
	<b>Examiner</b> JAMES H. ALSTRUM ACEVEDO	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,11-14,17,19-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,11-14,17,19-23 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/21/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Claims 1, 3-6, 11-14, 17, 19-23, and 25-28 are pending.** Applicants previously cancelled claims 2, 7-10, 15-16, 18, 24, and 29-32. Applicants amended claims 1, 3-6, 20-22, and 25-26. Applicants are advised that a different Examiner is examining the instant application. The petition decision of May 20, 2009 denying Applicants benefit of priority to prior-filed non-provisional application 09/878,558 is acknowledged. Receipt and consideration of Applicants' amended claim set and remarks/arguments are acknowledged.

### ***Priority***

This Application is denied benefit of parent application 09/162,587 (now U.S. Patent No. 6,284,266), because the instant application was filed on September 18, 2001 and parent application 09/162,587 issued on September 4, 2001. Thus, the instant application was not copending with parent application 09/162,587. It is also noted that the temperature ranges recited in claims 14, 19, and 27 and claim 21 of the instant application are not supported by the specification of parent application, 09/162,587. Because parent application 09/162,587 was a CON of grandparent application 09/545,496, grandparent application 09/545,496 also lacks support for claims 14, 19, 21, and 27. **The effective filing date of the instant application is thus, September 18, 2001.**

### ***Terminal Disclaimer(s)***

The terminal disclaimers filed on 11/14/2005 and 5/27/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date

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of U.S. Patent Nos. (i) 6,245,347 [submitted 11/14/05], (ii) 6,488,959 [submitted 11/14/05], (iii) 6,756,053 [submitted 11/14/05], and (iv) 6,284,266 [submitted 5/27/03] have been reviewed and are accepted. The terminal disclaimers have been recorded.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

**The specification is objected** to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification, as written, lacks support for original claims 20-21. Applicants are kindly requested to amend the specification to include the limitations of original claims 20-21.

### ***Claim Objections***

**Claim 21 is objected** to because of the following informalities: the word “comprises” should be replaced by the word “has”, because a composition of matter does not comprise its own properties, but rather "has" or "exhibits" its properties. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 3-6, 11-14, 17, 19-23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. U.S. Patent No. 5,919,479 (Zhang) in view of Brown et al. (US 2003/0060479), as evidenced by Stedman's Medical Dictionary, 25<sup>th</sup> edition, William Wood and Company: 1990, Baltimore, pp 65, 75, and 77.**

### *Applicant Claims*

Applicants claim (1) a method comprising (i) delivering an analgesic through the skin of a patient by using a dermal drug delivery system (DDDS), (ii) applying a temperature modification apparatus proximate to the delivery site on the skin, wherein the DDDS is a separate device from the temperature modification device, which comprises (a) a shallow chamber defined by an air impermeable material, said chamber having at least one side that allows air to enter into said chamber at a pre-determined rate, (b) a heat generating medium disposed within said chamber, and (iii) heating said skin with said temperature modification apparatus to a pre-determined temperature range and pre-determined duration; and (2) a dermal drug delivery system comprising a transdermal patch for the delivery of an analgesic transdermally and a temperature control apparatus securable to said patch (i.e. a temperature modification device), as described above.

### *Determination of the Scope and Content of the Prior Art (MPEP §2141.01)*

Zhang teaches noninvasive **dermal anesthetic delivery** using **an apparatus comprising a thin drug formulation reservoir (i.e. transdermal patch) and a heat generating apparatus (i.e. a temperature modification device) separated from the reservoir by a first non-permeable wall** (title; abstract). The term “non-permeable wall” reads on air-impermeable material. The heat generating device utilizes a chemical heat generating composition comprising **iron powder, water, activated carbon, and/or salt (i.e. sodium chloride)**, wherein this composition provides the advantages of being low cost, a high thermal energy per unit mass, rapid onset of heating, light weight, controlled and relatively stable heating temperature over

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extended duration, and independent operation (col. 10, line 63 through col. 11, line 13). **The rate of heating and the temperature are controlled by regulating the air flow reaching the heat generating composition through openings in the heat generating apparatus** (col. 11, lines 20-26; Figure 2; and col. 11, line 49 through col. 12, line 26). Zhang teaches that it is known that skin permeability to pharmaceutically active agents is significantly affected by skin temperature (col. 10, lines 43-47). Zhang's invention provides a **device with the capacity to heat and regulate skin temperature to a desired and elevated narrow range for a sufficient length of time**. Zhang focuses on the delivery of **anesthetics, such as tetracaine and lidocaine**, but teaches that **the pharmaceutical delivery device can be used to deliver a multitude of drugs** (col. 7, lines 5-26). Zhang's device also includes **an adhesive or adhesives to affix the heat generating device to the skin**, wherein the heat generating device is a separate device from the drug reservoir device (i.e. transdermal patch) (col. 12, lines 9-27).

Brown teaches that transdermal patches (i.e. dermal delivery devices) comprising analgesics (e.g. fentanyl) are well known in the art ([0002] and [0006]). Brown also teaches that **fentanyl and its derivatives (e.g. sufentanil) are art-recognized anesthetics and analgesics** [0011].

Stedman's defines an **anesthetic as a compound that reversibly depresses neuronal function producing the loss of ability to perceive pain** and/or other sensations (pg. 77). **An analgesic is a compound that relieves pain by altering perception of nociceptive stimuli...** (*Id.* at 65).

*Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)*

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Zhang lacks the express teaching of the delivery of analgesics and a device comprising analgesics. This deficiency is considered prima facie obvious in part by the teachings of Brown and in part per the teachings of Zhang, as explained below.

***Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)***

It would have been prima facie obvious at the time of the instant invention to modify the teachings of Zhang to include an analgesic as the drug delivered by Zhang's invented dermal delivery device and temperature modifying apparatus, because the transdermal devices delivering analgesics are well known. An ordinary skilled artisan would have been motivated to utilize analgesics, because both analgesics and anesthetics are art-recognized to provide treatment for the treatment of pain. For example, Stedman's 25<sup>th</sup> edition medical dictionary defines an anesthetic as a compound that reversibly depresses neuronal function producing the loss of ability to perceive pain and/or other sensations (pg. 77). Similarly, analgesics are known to be suitable for the treatment of pain by relieving the perception of nociceptive stimuli (Id. at 65). Some anesthetics are also generally used as analgesics (e.g. fentanyl and sufentanil) (Brown). An ordinary skilled artisan would have been capable to select the appropriate pain relieving compound (an analgesic, anesthetic, or combination thereof) suitable for the treatment of a particular perception of physical pain. Thus, an ordinary skilled artisan would have had a reasonable expectation of success upon utilizing an analgesic in Zhang's dermal drug delivery device, because the transdermal delivery of analgesics is well known (Brown) and both analgesics and anesthetics are art-recognized as providing treatment of pain.

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Regarding the particular temperature range, the optimization or modification of the temperature in a process/method is *prima facie* obvious. An ordinary skilled artisan would have had a reasonable expectation of successfully modifying the temperature applied to the skin, because Zhang's heat generating device contains features to attenuate the oxygen reaching the heat generating mixture and thus the rate of reaction and the resulting heat (i.e. temperature) from the exothermic reaction of the oxygen and the heat generating medium. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**Claims 1, 5-6, 11-14, 17, 19-23, and 25-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-42 of U.S. Patent No. 6,340,472 (USPN '472).** Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets claim (i) methods comprising the delivery of a drug (e.g. analgesic) through the skin via a dermal drug delivery device and (ii) the application of a heat generating device characterized by a shallow chamber defined by an air impermeable wall having openings and comprising a heat generating medium that undergoes an exothermic reaction upon exposure to oxygen. The differences between the claim sets are described below as well as why these differences merely represent obvious modifications.

The primary difference between independent claims 40-41 of USPN '472 and the cited method claims of the instant application (i.e. 1, 4-6, 17, 19, 21, 23, and 28) is that independent claims 40-41 of USPN '472 do not recite that the heat generating device comprises a shallow chamber defined by an air impermeable wall (i.e. material). The utilization of a heat generating device with a shallow chamber represents a design choice. The incorporation of an air-impermeable material is an obvious modification of the method of claims 40-41 of USPN '472, because the heat generating medium of USPN '472 undergoes reaction with oxygen. Thus, it would have been *prima facie* obvious to an ordinary skilled artisan to utilize air impermeable materials to control the rate of the exothermic reaction of the heat generating medium with oxygen. Regarding the use of an analgesic as the drug to be delivered, this is an obvious modification, as evidenced by claims 41-42 of USPN '472. Regarding the temperature range, the temperature range recited in the claims of USPN '472 overlap with or are encompassed by the temperature ranges recited in Applicants' claims. A *prima facie* case of obviousness

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necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05.

Regarding the removal of the heating apparatus prior to causing an adverse effect or after achievement of the desired clinical result, this is nothing more than common sense. It is plainly obvious that no ordinary skilled artisan would intentionally continue application of the heating apparatus to a patient's skin to the point of injury. It is the Examiner's position that the ordinary skilled artisan would be wary and mindful of preventing unnecessary injury to a person receiving treatment. Similarly, the ordinary skilled artisan would be cognizant of the dangers of overdosage and would readily discontinue treatment once the desired clinical effect (e.g. diminishment of breakthrough pain) was achieved. Regarding the heat generating medium, it is obvious that the specification of USPN '472 contemplates that the heat generating medium would be a mixture of iron, activated carbon, and sodium chloride (col. 12, lines 55-63). The use of adhesives to affix the heat generating device to the dermal drug delivery device and/or to the skin is *prima facie* obvious, because adhesives are conventional means of affixing items to one another and/or to the skin. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 5-6, 11-14, 17, 19-23, and 25-28 *prima facie* obvious over claims 40-42 of U.S. Patent No. 6,340,472 (USPN '472).

**Claims 1, 3-6, 11-14, 17, 19-23, 25, and 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 5 of U.S. Patent No. 6,780,426 (USPN '426).** Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets claim (i) methods

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comprising the delivery of a drug (e.g. analgesic) through the skin via a dermal drug delivery device and (ii) the application of a heat generating device characterized by a shallow chamber defined by an air impermeable wall having openings and comprising a heat generating medium that undergoes an exothermic reaction upon exposure to oxygen. The differences between the claim sets are described below as well as why these differences merely represent obvious modifications.

The primary difference between independent claim 2 of USPN '426 and the cited method claims of the instant application (i.e. 1, 4-6, 17, 19, 21, 23, and 28) is that independent claim 2 of USPN '426 does not recite the specifics of the heat generating device, namely a shallow chamber defined by an air impermeable wall (i.e. material). The utilization of a heat generating device with a shallow chamber is an obvious modification of the method of claim 2 of USPN '426 as evidenced, by independent claim 5 of USPN '426 and col. 7, line 61 through col. 8, line 15. Regarding the use of an analgesic as the drug to be delivered, the specification of USPN '426 identifies analgesics among many drug classes indicated as being suitable for the claimed method (col. 26, lines 45-54). It is proper to turn to a patent's or application's disclosure as a dictionary and/or to understand the scope of what is meant by a term in a claim and what constitutes an obvious modification. This position is supported by the courts. See *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Regarding the temperature range, it is generally considered *prima facie* obvious to modify temperature in an effort to optimize processes and methods. Regarding the removal of the heating apparatus prior to causing an adverse effect or after achievement of the desired clinical result, this is nothing more than common sense. It is plainly obvious that no ordinary skilled artisan would intentionally continue application of the

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heating apparatus to a patient's skin to the point of injury. It is the Examiner's position that the ordinary skilled artisan would be wary and mindful of preventing unnecessary injury to a person receiving treatment. Similarly, the ordinary skilled artisan would be cognizant of the dangers of overdosage and would readily discontinue treatment once the desired clinical effect (e.g. diminishment of breakthrough pain) was achieved. Regarding the heat generating medium, it is obvious that the specification of USPN '426 contemplate that the heat generating medium would be a mixture of iron, activated carbon, and sodium chloride (i.e. a major component of sea salt) (col. 7, line 67 through col. 8, line 2). The use of adhesives to affix the heat generating device to the dermal drug delivery device and/or to the skin is also contemplated by USPN '426. (col. 7, lines 48-51). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 4-6, 11-14, 17, 19, 21-23, 25, and 27-28 *prima facie* obvious over claims of claims 2 and 5 of U.S. Patent No. 6,780,426 (USPN '426).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhang (2002/0004063) is considered relevant, because it teaches methods and apparatus for the transdermal delivery of drugs and identifies that local anesthetics are art-recognized as provided some analgesia [0011].

**Claims 1, 3-6, 11-14, 17, 19-23, and 25-28 are rejected. Claim 21 and the specification are objected. No claims are allowed.**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner is on a flexible schedule, but can normally be reached on M-F ~10am~5:30 pm, and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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